TECHNICAL REVIEW AND EVALUATION
OF APPLICATION FOR
AIR QUALITY PERMIT NO. 42509

I. INTRODUCTION

This renewal permit is for the operation of a facility manufacturing sterile medial devices by Tri-State Hospital Supply Corporation. This is a stationary facility located in Yuma, Yuma County, Arizona. This is a renewal of Permit #1001586.

Company Information

Mailing Address: 3173 E 43rd Street
Yuma, AZ 85365

Facility Address: 3173 E 43rd Street
Yuma, AZ 85365

II. FACILITY/PROCESS DESCRIPTION

A. Process Description

Tri-State Hospital Supply Corporation manufactures sterile medial devices. Part of manufacturing process includes sterilization by means of Ethylene Oxide (ETO). These activities are carried out in Yuma, Arizona.

The sterilization process consists of three basic stages; preconditioning, sterilization, and aeration. **Preconditioning**, the first stage in the sterilization process requires non-sterile, pre-packaged, cartoned and palletized medical devices to be "preconditioned". This allows the non-sterile materials to "incubate" at controlled temperature and humidity before being moved on to the sterilization stage. During the **sterilization** process, pre-packaged medical devices are exposed to ETO gas, which destroys the living microorganisms present on the devices. The sterilization process utilizes one of the three sterilization chambers. The sterilization cycle consists of several steps that take place under various levels of negative pressures. After the preconditioned pallets have been placed into a chamber, vacuum pumps draw air from the chamber. Nitrogen is then injected to purge the air remaining in the chamber. This phase is known as "nitrogen dilution". Steam from electric boilers is added to the chamber for attaining the desired humidity. Sterilant gas, ETO, is then injected followed by a blanket of nitrogen. This phase is known as "exposure". Following the exposure phase, ETO is evacuated. This phase is known as "sterilant removal". The sterilant removal phase and all subsequent washes are referred to as sterilization chamber vent (SCV). Following sterilization, pallets are moved into the aeration room. In this room, the sterilized product is allowed to further reduce the residual traces of ETO. The aeration room is maintained under slight negative pressure by pulling ETO laden gases through a control device exhausted to atmosphere. This air stream is called aeration room vent (ARV). By design, the aeration room is continuously operated under negative pressure and make-up air is

continuously drawn in from the transfer corridor, thus further minimizing any potential fugitive ETO emissions.

B. Air Pollution Control Equipment

For controlling ETO emissions to the atmosphere from the sterilization facility, Tri State Hospital Supply Corporation use a thermal oxidizer and three dry-bed scrubbers. The SCV air stream is controlled by a thermal oxidizer operating at or above a minimum temperature capable of achieving at least 99 percent ETO destruction efficiency. The ARV air stream is controlled by three dry-bed scrubbers. The dry-bed scrubbers are capable of achieving destruction efficiency of at least 99 percent or to a 24-hour average no greater than 1 ppmv, whichever is less stringent.

III. POTENTIAL TO EMIT

There are three sterilization chambers and one aeration room in the facility. Potential to emit from the facility based on two cycles per day per sterilizer, 365 days a year is 0.724 tons of ETO per year. Thermal oxidizer which uses natural gas as the fuel emits out negligible quantities of NO_x and CO (0.35 and 0.30 tons per year respectively).

IV. COMPLIANCE HISTORY

Tri-State Hospital Supply Corporation has not been issued any Notices of Violation (NOVs) till date.

V. PREVIOUS PERMITS

TABLE 1: PREVIOUS PERMITS

Previous Permit	Date Issued
Permit #1001586	May 9, 2002

VI. PREVIOUS PERMIT CONDITIONS

Table 2 compares the conditions in Permit #1001586 with the conditions in this permit and cross-references the previous permit conditions to their location in the new permit.

TABLE 2: PREVIOUS PERMIT CONDITIONS

Condition # in permit number 1001586	Determination				Comments
	Delete	Kept	Revise	Streamline	
Attachment A			x		Most recent attachment is used for this permit.
Attachment B					
Condition I.		x			This Condition removed since it is a renewal permit.
Condition II.A.1 and II.A.2		x			These have been renumbered as Condition II.A.1, II.A.2, and II.A.3
Condition II.A.3				x	The requirements for Air Pollution Control have been streamlined and placed in Condition II.B.
Condition II.B and II.D				x	The requirements for Compliance and Performance Testing have been streamlined and placed as Testing Requirements in Condition II.C.
Condition II.C, E, and F				x	The requirements for monitoring, reporting, and recordkeeping have been streamlined and placed as Monitoring, Reporting and Recordkeeping requirements in Condition II.D
Condition II.G				x	Permit Shield has been streamlined and placed as Condition II.F.

VII. APPLICABLE REGULATIONS

TABLE 3: VERIFICATION OF APPLICABLE REGULATIONS

Unit	Date of Manufacture	Control Device	Rule	Verification
Sterilization Chambers,	2001, 1991, 2006	Natural gas fired thermal oxidizer.	40 CFR §63.362.(b), 40 CFR §63.362.(c), 40 CFR §63.362.(d), 40 CFR §63.363.(b)(3), 40 CFR §63.363.(f), 40 CFR §63.364.(a)(1), 40 CFR §63.364.(c), 40 CFR §63.364.(c)(4), 40 CFR §63.364.(d), 40 CFR §63.364.(e), 40 CFR §63.365.(a), 40 CFR §63.365.(b), 40 CFR §63.365.(c), 40 CFR §63.366.(a), 40 CFR §63.366.(a)(1), 40 CFR §63.366.(a)(2), 40 CFR §63.366.(b), 40 CFR 63.366(c) and 40 CFR §63.367.(a)	Subpart O-Ethylene Oxide Emissions Standards for Sterilization Facilities
Aeration Room	2001	Three dry-bed scrubbers.		
Fugitive dust sources	N/A	Water and other reasonable precautions.	A.A.C. R18-2-604.A, A.A.C. R18-2-604.B, A.A.C. R18-2-605, A.A.C. R18-2-606, A.A.C. R18-2-607, and A.A.C. R18-2-612	These standards are applicable to all fugitive dust sources.
Mobile Sources	N/A	Water Sprays/Water Truck for dust control	A.A.C. R18-2-801, A.A.C. R18-2-802, and A.A.C. R18-2-804	This Article is applicable to off-road mobile sources, which either move while emitting air pollutants or are frequently moved during the course of their utilization.
Spray painting operations	N/A	N/A	A.A.C. R-18-2-727,	This standard is applicable to any spray-painting operation.
Demolition/renovation operations	N/A	N/A	A.A.C. R18-2-1101.A.8	This standard is applicable to any asbestos related demolition or renovation operations.

VIII. MONITORING, RECORD KEEPING, AND REPORTING REQUIREMENTS

A. The Permittee must continuously monitor and record the oxidation temperature at the exhaust point from the thermal combustion chamber using the temperature monitor. This is to ensure that the thermal oxidizer is being operated at a temperature above the minimum oxidation temperature recommended by the vendor.

B. The Permittee shall measure and record once per hour, the ETO concentration from the aeration room vent, before and after the dry-bed scrubbers using the gas chromatograph. The Permittee must compute and record a 24-hour average daily.

IX. TESTING REQUIREMENTS

The Permittee must perform tests annually on the thermal oxidizer and dry-bed scrubbers to show compliance with the emission limits.

X. LEARNING SITES POLICY

In accordance with ADEQ's Environmental Permits and Approvals near Learning Sites Policy, the Department conducted an evaluation to determine if any learning sites would be adversely impacted by Tri- State Hospital Supply Corporation. Learning sites consists of all public schools, charter schools and private schools at the K-12 level, and all planned sites for schools approved by the Arizona School Facilities Board. The learning sites policy was established to ensure that the protection of children at learning sites is considered before a permit is issued by ADEQ.

The Department did not find any learning site within two miles of the facility.

XI. LIST OF ABBREVIATIONS

A.A.C. ..... Arizona Administrative Code
ADEQ ..... Arizona Department of Environmental Quality
AQD ..... Air Quality Division
ARV ..... Aeration Room Vent
CFR ..... Code of Federal Register
CO ..... Carbon Monoxide
ETO ..... Ethylene Oxide
NO_x ..... Nitrogen Oxide
SCV ..... Sterilization Chamber Vent